EXHIBIT D

AMERICAN ASSOCIATION FOR HOMECARE

Formed By The Organizations of HHA Home Care, HHSA and NAMES

Supporting Quality Health Care Services at Home

Via Fed. Ex.

October 3, 2000

Dr. Adrian Oleck
DMERC Regional B
Adimimistar Federal
8115 Knue Road
Indianapolis, In 46350

Re: **Medicare Reimbursement of Prescription Drugs Covered Under Part B**

Dear Dr. Oleck:

On behalf of the American Association for Homecare (AAH), I want to provide you with some background information on the Health Care Financing Administration's (HCFA's) proposal to change Medicare reimbursement for prescription drugs covered under Part B. As you know, on September 8, 2000, HCFA released to its carriers a program memorandum containing new average wholesale prices (AWP) for most of the drugs covered under Part B. Specifically excluded from the new pricing formulas are most of the drugs used in cancer therapies and the drugs used to treat hemophilia patients.

Importantly, the program memorandum *does not mandate* that the carriers adopt the new AWPs. Rather, HCFA suggests that carriers should *consider* adopting the new prices in their next quarterly update effective January 1, 2001. Changes in reimbursement that result from the new pricing would affect Medicare beneficiaries with respiratory conditions, dialysis patients, and patients receiving other infusion therapies in the home. In many cases, the new AWP would reduce reimbursement for the therapy to below the supplier's acquisition cost for the drug.

We are concerned that this proposal fails to consider the effect of such drastic reductions on Medicare beneficiaries' ability to receive these therapies in their homes. In order to administer these therapies safely and effectively, suppliers are required to provide services that are not separately reimbursed by the Medicare program. Drastically limiting the reimbursement for these drugs will curtail the supplier's ability to provide the drug and the required services to beneficiaries, ultimately reducing Medicare beneficiaries' access to the drugs. Ironically, an initiative intended to reduce costs to the Medicare program will result in greater overall costs because beneficiaries will be forced to receive care in more expensive settings such as hospitals. Beneficiaries also will experience a higher rate of emergency room visits.

Given these concerns, AAH asked The Lewin Group to study and report on the impact of HCFA's proposed changes to the AWP. A copy of the study is enclosed. The Lewin report

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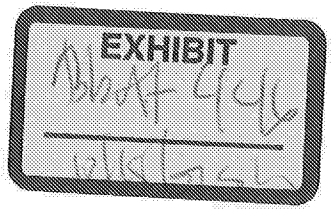

documents the impact that these reductions will have on access. Specifically, the report concludes that:

- Medicare and Medicaid patients' access to respiratory and infusion drug therapies will diminish as firms reduce services in public sector markets. One pharmacist observed to The Lewin Group, "I could service patients one whole year for what it will cost Medicare for a day when the patient ends up in the emergency room."

- All companies surveyed would experience an operating loss for these pharmaceutical services, averaging 93 percent, as a result of proposed AWP reductions.

- The total cost of providing respiratory and infusion drug therapies in the home to Medicare and Medicaid patients far exceeds the cost of acquiring the drugs.

The decision by HCFA to go forward with some reimbursement reductions and postpone others only compounds the problem. Clearly patients with chronic lung diseases, or who require certain targeted drugs during their kidney dialysis treatments, will disproportionately bear the brunt of the pricing changes. It is important to remember that drug manufacturers set the AWP – suppliers do not play a role in that process. Thus, while the change in reimbursement affects suppliers and, in turn, beneficiaries directly, it will do nothing to affect the larger issue of drug pricing at the source. Likewise, changes in Medicare reimbursement for covered drugs must include appropriate consideration of the services that are essential to the therapy. HCFA's proposal does not consider these important issues.

We urge you to carefully consider these issues as the durable medical equipment carrier (DMERC) for your respective regions determines whether to adopt the new AWP for drugs suggested by HCFA. We have enclosed a copy of the Lewin report as well as correspondence from members of Congress and the medical community voicing their concerns about HCFA's proposal. We remain willing to have a meaningful discussion with you and your colleagues at the other DMERCs regarding this issue and are available to meet with you at your convenience.

If you have any questions, please feel free to call me.

Sincerely,

Asela M. Cuervo
Vice President Government Affairs

AMERICAN ASSOCIATION FOR HOMECARE

Formerly the Organizations of HIDA Home Care, IHSSA and NAMES

Supporting Quality Health Care Services at Home

AMERICAN ASSOCIATION FOR HOMECARE
AWP BACKGROUND MATERIALS

CONTENTS

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NATIONAL ASSOCIATION FOR MEDICAL DIRECTION OF RESPIRATORY CARE
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August 15, 2000

Robert Berenson, MD
Director, Center for Health Plans
Health Care Financing Administration
200 Independence Avenue, SW Room 314G
Washington, DC 20201

Dear Dr. Berenson:

It has recently come to our attention that the Health Care Financing Administration is considering a reduction in the current Medicare payment amount for albuterol sulfate, possibly by as much as 60%.

We readily concede that as an organization of pulmonary physicians our expertise in the pricing of pharmaceuticals is limited, but our experience as well as logic indicate that such a cut would likely have a dramatic and adverse effect upon access to albuterol sulfate by many of our patients.

The most common scenario for Medicare coverage of albuterol is through the durable medical equipment (DME) benefit which, as you well know, includes coverage of nebulizers and the related drug used in the nebulizer. It has generally been our experience that home care companies provide a distinct level of "value added" services regarding nebulizers and the accompanying drug (albuterol). Most importantly, they monitor the patient for compliance with a particular treatment plan, informing the prescribing physician when compliance becomes problematic or another, related problem arises. If the payment amount is reduced by 60%, we are extremely concerned that many home care companies will no longer provide this key aspect of disease management, perhaps going as far as to no longer accept such patients.

It is our understanding that a fair amount of anecdotal evidence of this likelihood is already apparent in certain state Medicaid programs where payment cuts have already been instituted. It is only logical that similar, or deeper, cuts in the Medicare pricing formula would have a similar impact upon beneficiary access to need medications.

It is important to emphasize that we, too, recognize the spiraling cost of pharmaceuticals. As practicing physicians it can be extremely challenging and frustrating to prescribe drugs for our patients knowing that the financial cost of adherence to the drug regimen can be prohibitively costly to the patient, the Medicare program and/or the private insurance company. In candor, however, it seems a little backwards to modify a drug payment policy that would have a negative impact on Medicare beneficiaries and only a questionable

impact on the actual drug manufacturer(s).

It has been long standing policy of NAMDRC to work as closely as possible with HCFA on pulmonary/critical care issues, offering reasonable alternatives and compromises. While we are still wrestling with pulmonary rehabilitation, in recent months our collective compromises on critical care and non invasive positive pressure ventilation issues reflect, I believe, our joint willingness to craft reasonable policies that are driven by the best possible practice of medicine. Unfortunately, we are unable to suggest a compromise on this matter simply because, as I mentioned earlier, drug pricing is not an area of our expertise. We do urge you, however, to consider that a dramatic cut in the price of albuterol may not only inhibit access to albuterol but, in the long run, may increase Medicare program costs because of a drop in beneficiary compliance with appropriate drug regimens and overall treatment plans, thereby increasing the number of encounters by the Medicare beneficiary with the health care system.

I appreciate your consideration of these comments.

Sincerely,

Paul A. Selecky, MD
President

Impact of Proposed AWP Reductions on the Provision of Home Drug Therapies to Medicare and Medicaid Patients

American Association for Homecare
September 8, 2000

The Lewin Group

Falls Church, Virginia • San Francisco, California • Boston, Massachusetts
Montreal • London • Paris • Amsterdam

Impact of Proposed AWP Reductions on the Provision of Home Drug Therapies to Medicare and Medicaid Patients

Prepared for:
American Association for Homecare
September 8, 2000

By:
Allen Dobson, Ph.D.
JoAnn Lamphere, Dr.P.H.
Lane Koenig, Ph.D.
Jennifer Babcock

The Lewin Group

EXECUTIVE SUMMARY

The American Association for Homecare retained The Lewin Group in July 2000 to examine the potential consequences of a change in Medicare drug reimbursement policy for home pharmaceutical providers. The Association's impetus for commissioning the study was a May 31, 2000 announcement from the Department of Health and Human Services (DHHS) that it intended to reduce Medicare Part B payments for specific drug therapies and fundamentally alter the method by which certain drug therapies are reimbursed. Proposed Medicare drug payment changes are scheduled to go into effect on October 1, 2000. The DHHS announcement follows on the heels of a Department of Justice recommendation to state Medicaid programs to adopt new (and reduced) pricing for nearly 400 national drug codes.

In this paper we estimated the cost structure of providing respiratory and infusion drug therapies in the home setting and the impact of adopting proposed reductions in Medicare Part B and Medicaid reimbursement for these drugs. Key findings include:

- The total cost of providing respiratory therapy and infusion drugs in the home to Medicare and Medicaid patients far exceeds the cost of acquiring the actual drug itself.
- All companies surveyed would experience an operating loss for these pharmaceutical services, averaging 93 percent, as a result of proposed AWP reductions.
- The companies projecting the greatest percentage losses are those that are the largest, have operations in many states, and generally serve the highest proportion of Medicare patients.
- Medicare and Medicaid patients' access to respiratory and infusion drug therapies will diminish, as a result, as firms reduce services in public sector markets.

BACKGROUND AND SIGNIFICANCE

The issue of drug pricing is receiving considerable and increasing attention among public and private policymakers. Concern is being expressed by members of Congress, the Office of Inspector General at the Department of Health and Human Services, and the Department of Justice about the levels of Medicare and Medicaid reimbursement for certain pharmaceuticals and drug therapies. Many policymakers assert these levels are "excessive" because reimbursement is based on an average wholesale price (AWP). This is because large purchasers of pharmaceuticals often receive substantial discounts from manufacturer's listed prices; if viewed by itself, the payment for certain drug products may appear high. This perspective is arguably narrow, however, given the economics of the home pharmacy industry. The difference between what companies are paid by Medicare and Medicaid (a percentage of AWP) and their "true" drug acquisition costs is the only way providers of home drug therapies are able to provide ongoing professional services integral to quality patient care under current payment arrangements.

The Department of Health and Human Services announced on May 31, 2000 that it is moving administratively to reduce Medicare payments for select drug therapies. For Medicare Part B

claims, DHHS intends to pay the "average wholesale catalog price," compiled by the Department of Justice and recommended for state Medicaid programs. Although First Data Bank (FDB) recalculated wholesale drug prices for nearly 400 national drug codes, the method used by FDB has not been made publicly available. Resulting Medicare drug payment changes are scheduled to become effective October 1, 2000.

The Lewin Group has completed its analysis of data collected from mail and telephone surveys of providers. The following is a report of what was learned through this effort.

ANALYSIS AND APPROACH

Study Objectives

The Lewin Group conducted a study for the American Association for Homecare during July-August 2000 that estimated the cost structure of providing respiratory and infusion drug therapies in the home setting and the financial impact of adopting proposed reductions in Medicare Part B and Medicaid reimbursement for these drugs. As part of this study, The Lewin Group assessed the potential effect of these reimbursement changes on Medicare and Medicaid patients who receive drug therapies in the home.

Sample

Data were obtained from 12 providers of home medical equipment and pharmaceutical services, specifically respiratory and infusion therapies, who completed a written survey instrument and a telephone interview. The sample is believed to be generally representative of home pharmaceutical companies nationally. Sampled companies range in size from less than $1 million to $1 billion annual net revenue and serve Medicare and Medicaid patients in all geographic regions throughout the United States.

The sample was stratified by size of companies' volume of business. Small firms were defined as those with less than $5 million total annual revenue; large firms were those with $30 million or more in total annual revenue; and mid-sized firms were in-between.

Survey Design

The cost survey, designed in conjunction with industry financial experts, sought to calibrate the cost structure of the industry as it pertains to the provision of respiratory and infusion drug therapies in the home setting to Medicare and Medicaid patients. A chief financial officer (or designee) from each participating company completed the mail-in cost survey and participated in an extensive follow-up telephone interview.

The Lewin cost survey identified major categories of professional services that accompany the provision of drug therapies in the home (such as pharmacy, patient management, delivery, and others) and other corporate costs. Revenue and cost data were provided by surveyed companies and then proportionately allocated to the business unit providing respiratory and infusion services to patients whose care is covered by Medicare or Medicaid. Estimates of AWP

reductions were derived for approximately 50 drug categories listed in First Data Bank's compilation of drugs that would be affected by new pricing data (as of June 2, 2000), as communicated in a Department of Justice letter to State Medicaid directors. In addition to financial data, the survey and follow-up telephone interviews posed open-ended questions concerning the provider's assessment of the business impact of proposed AWP reductions in the Medicare and Medicaid sectors for those drug therapies under review. Finally, participants provided their perceptions of the consequences in terms of access, quality, and cost for Medicare and Medicaid patients who receive the drug therapies considered for AWP reductions.

Analysis

Average company financial losses for Medicare and Medicaid sources and ranges of losses were projected under the new AWPs by determining profit ratios for each company, both before and after AWP reductions. Cost data were analyzed for small, medium and large companies by averaging categories of cost (patient service costs, non-patient related costs, and drug acquisition costs) and calculating ratios of specific cost categories to total cost. Qualitative information was categorized and summarized from the telephone interviews.

FINDINGS

Value of Services Provided to Medicare and Medicaid Patients

The cost to a home pharmaceutical company of acquiring respiratory and infusion drugs is small in comparison to the total cost of services included in the provision of these drug therapies to Medicare and Medicaid patients. Surveys revealed that companies provide many essential professional services as part of delivering respiratory and infusion therapies in the home. These services include ongoing patient education, clinical monitoring of patients, nursing care, care coordination and management, emergency response, delivery, and others.

Assuring quality patient care and meeting established patient quality standards (e.g., JCAHO, federal and state licensure and regulatory requirements, customer service, education and training, emergency response, sanitary guidelines, and so forth) is an essential dimension of the service home medical companies offer to *all* patients and is often required for Medicare participation. The cost of assuring quality care is considerably greater than the cost of "a reasonable handling fee" that some policymakers have stated they would consider negotiating with providers.

A key finding of the study is that the total cost of patient management, pharmacy, quality assurance, delivery, medication storage, patient account services, storage, and company overhead is much greater than the acquisition cost of drugs (respiratory and home infusion therapy) for sample companies.

- Depending on company size, between 58 percent and 74 percent of the total costs of providing respiratory therapy and infusion drugs in the home to Medicare and Medicaid patients, on average, are not related to acquiring the pharmacy product (Figure 1). Note: in both Figures 1 and 2, average cost of pharmacy products is the acquisition price for the drugs; average cost of patient services includes the categories of patient management,

nursing, pharmacy and customer services; and average non-patient costs includes overhead, billing and collection, and storage and warehouse costs.

- If bad debt costs are excluded from revenue estimates, between 58 percent and 72 percent of the total costs of providing respiratory and infusion drugs in the home to Medicare and Medicaid patients, on average, are not related to acquiring the pharmacy product (Figure 2).

Financial Impact of Proposed AWP Reductions

- Companies providing respiratory and infusion drug therapies to Medicare and Medicaid patients at home may experience a 93 percent operating loss for these service components, on average, as a result of proposed AWP reductions. Loss was calculated as [net revenue post-AWP reductions minus costs] divided by net revenue post-AWP reductions.

- No company surveyed would remain profitable for the provision of home respiratory and infusion drug therapies to Medicare and Medicaid patients should the proposed AWP reductions be implemented. The estimated initial financial loss to companies as a result of proposed reductions ranges from 2 percent to 214 percent (Figure 3). If bad debt costs are excluded from financial loss estimates, only two companies expect to show any profit from Medicare and Medicaid services after AWP reductions (Figure 4). Note: in both Figures 3 and 4, sampled companies are arrayed in order of expected loss, not by size of company.

- The companies projecting the greatest percentage losses are those that are the largest and which have operations in many states. Two-thirds of the largest companies and three-quarters of mid-sized companies expect to experience a 50+ percent loss on studied services should proposed AWP reductions be adopted for the Medicare and Medicaid programs.

- Most of the companies with the greatest projected negative impact are those which serve a high proportion (>75 percent) of Medicare patients in their respiratory and/or infusion service areas.

Impact on Medicare and Medicaid Beneficiaries

- Medicare and Medicaid beneficiaries' *access* to respiratory and infusion drug therapies is expected to diminish should AWP reductions be adopted. Firms indicate they will reduce exposure in certain public sector markets. Companies report that they will be forced to curtail accepting new Medicare and Medicaid patients. Several companies assert they will exit the Medicare and Medicaid markets altogether.

- *Quality* may be jeopardized as companies limit ongoing patient monitoring and reduce staff.

- Ironically, Medicare patient *costs* could increase should proposed AWP reductions be adopted. Said one pharmacist, "I could serve patients one whole year for what it will cost Medicare for a day when they end up in the emergency room" [because of reduced access to in-home services]. In addition, some companies report they may stop accepting assignment for Medicare patients, thus increasing costs to the patient.

It is important for public policymakers to grasp the financial realities of the health care industry that provides respiratory and infusion services to Medicare and Medicaid patients in the home. Companies in this study's sample serve Medicaid patients in 31 states. Due to revenue losses from Medicaid AWP reductions for respiratory and infusion drug therapies, companies report they have begun curtailing acceptance of new Medicaid referrals, not accepting Medicaid beneficiaries who do not carry additional insurance, and departing from Medicaid markets in certain states. According to the National Home Infusion Association, by August 2000 seventeen states had adopted AWP reductions for the drug therapies under review. At the time the Lewin survey was conducted, companies had already begun curtailing services to new Medicaid patients in 15 of the 17 states that had adopted the Medicaid reductions.

CONCLUSION

High initial profit margins are no inoculation against the threat of proposed AWP reductions. If proposed AWP reductions for respiratory and infusion drug therapies are enacted for the Medicare and Medicaid programs, the financial health of all companies surveyed will be placed in jeopardy. Potential revenue reductions are so significant that all companies surveyed expect to experience operating losses as a result (for their respiratory and infusion home services to Medicare and Medicaid patients). For companies that serve a high proportion of Medicare and Medicaid patients, operating losses will be particularly severe.

Given these financial realities, companies affected by proposed AWP reductions intend to exit the Medicare market. Medicare beneficiaries will be negatively affected because they will experience reduced access to medically prescribed in-home services, potentially diminished quality of services and, in all likelihood, increased costs.

Lending credence to these conclusions is the real world experience of Medicaid. Sampled companies already have stopped serving new Medicaid patients in fifteen of the seventeen states that adopted reduced AWP pricing.

Federal and state governments' concerns with proper pricing of drug therapies must consider patient access and the unintended consequences of policy choices. The movement by Medicare and Medicaid towards simply paying for the acquisition costs of drug therapies is contrary to the economics of the home pharmacy industry. "Excess" revenue is needed to cover the additional wrap-around services associated with the provision of drug therapies and quality patient care. If AWP reductions are implemented, then it is essential to simultaneously adopt a reimbursement mechanism that recognizes the professional service component of providing these drug therapies, such as the private sector has done.

Figure 1: Estimated Distribution of Average Total Cost of Providing Respiratory Therapy and Infusion Drugs in the Home to Medicare and Medicaid Patients, by Company Size

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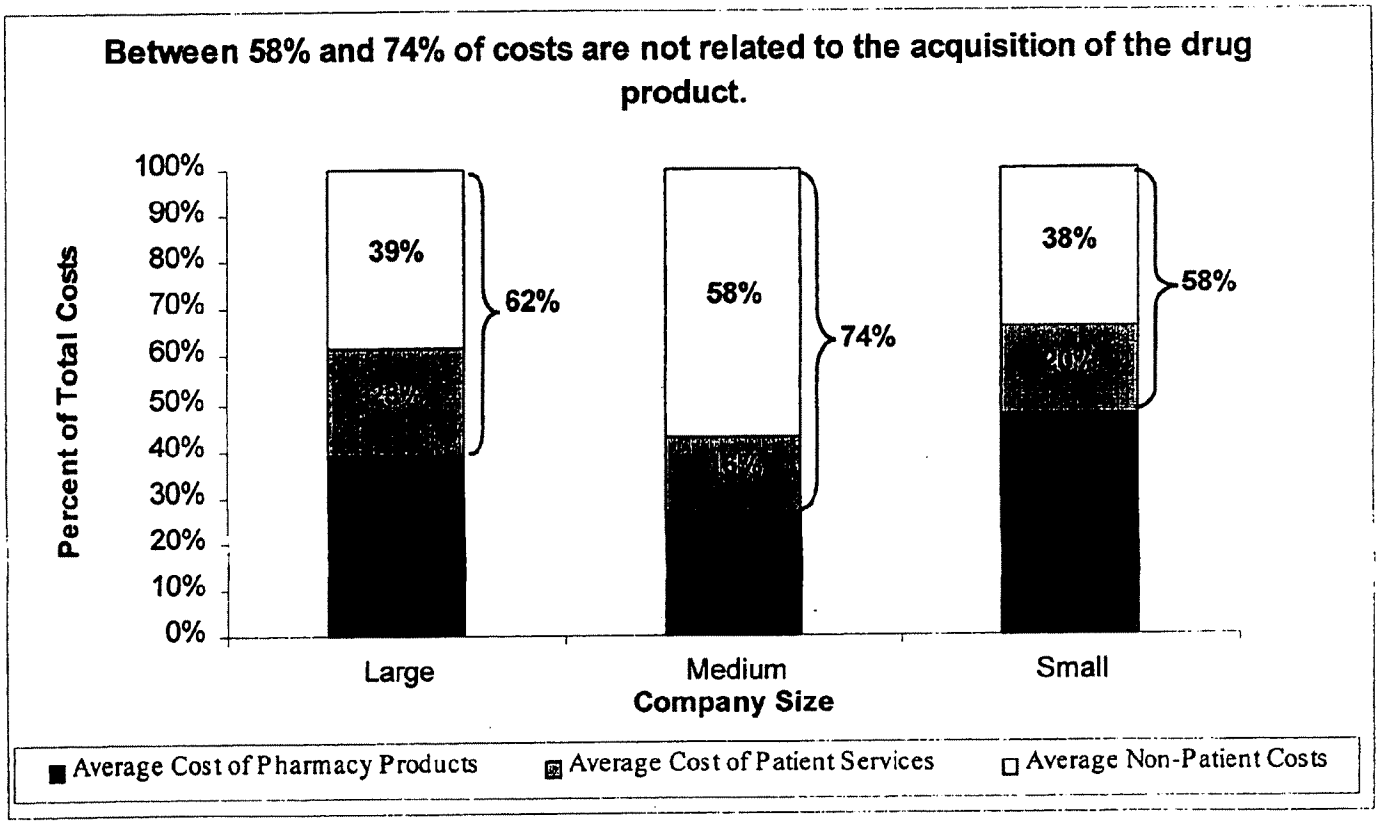

Sample Size = 12

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Figure 2: Estimated Distribution of Average Total Cost of Providing Respiratory Therapy and Infusion Drugs in the Home to Medicare and Medicaid Patients, by Company Size (excluding bad debt)

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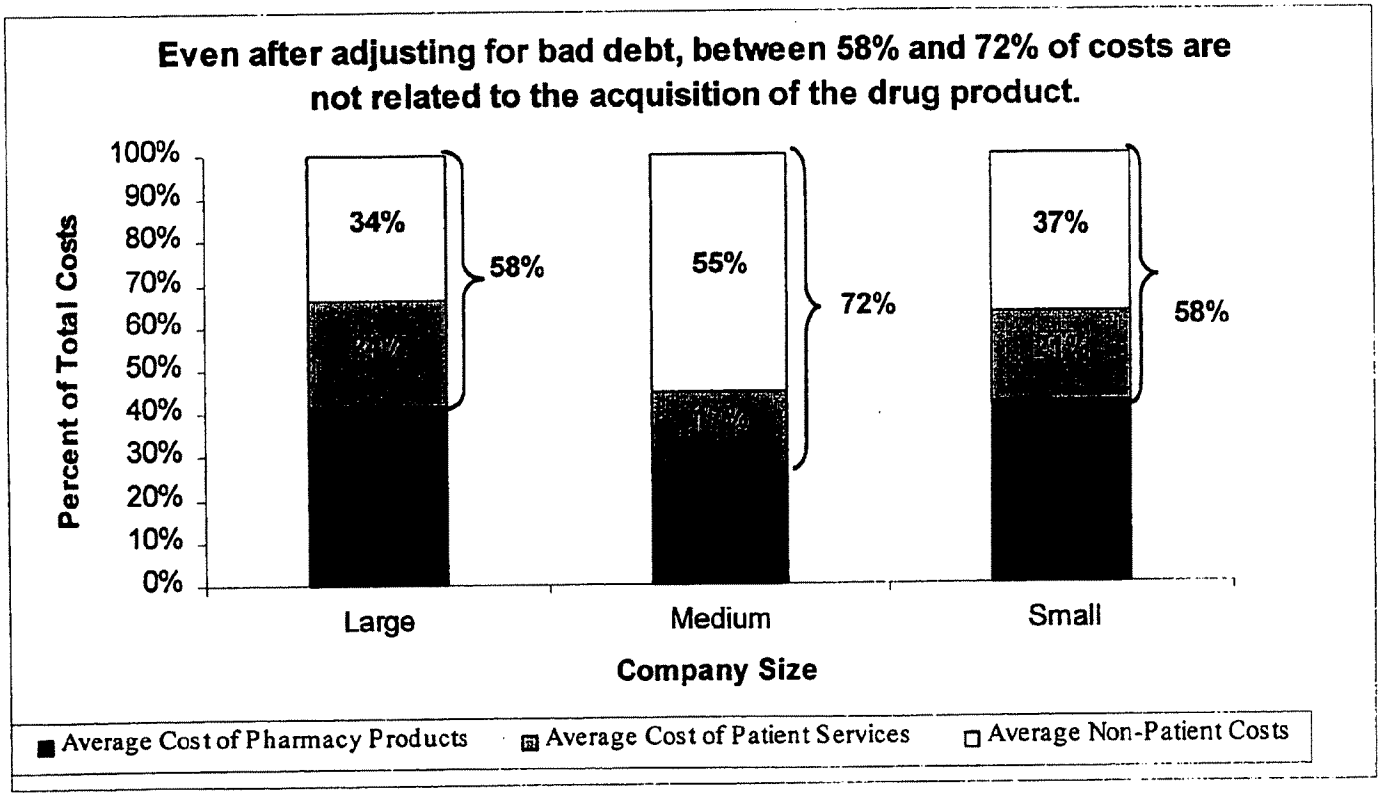

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Figure 3: Estimated Initial Financial Impact of AWP Reductions for Respiratory and Infusion Drug Therapies to Medicare and Medicaid Patients at Home by Individual Company

The LEWIN GROUP

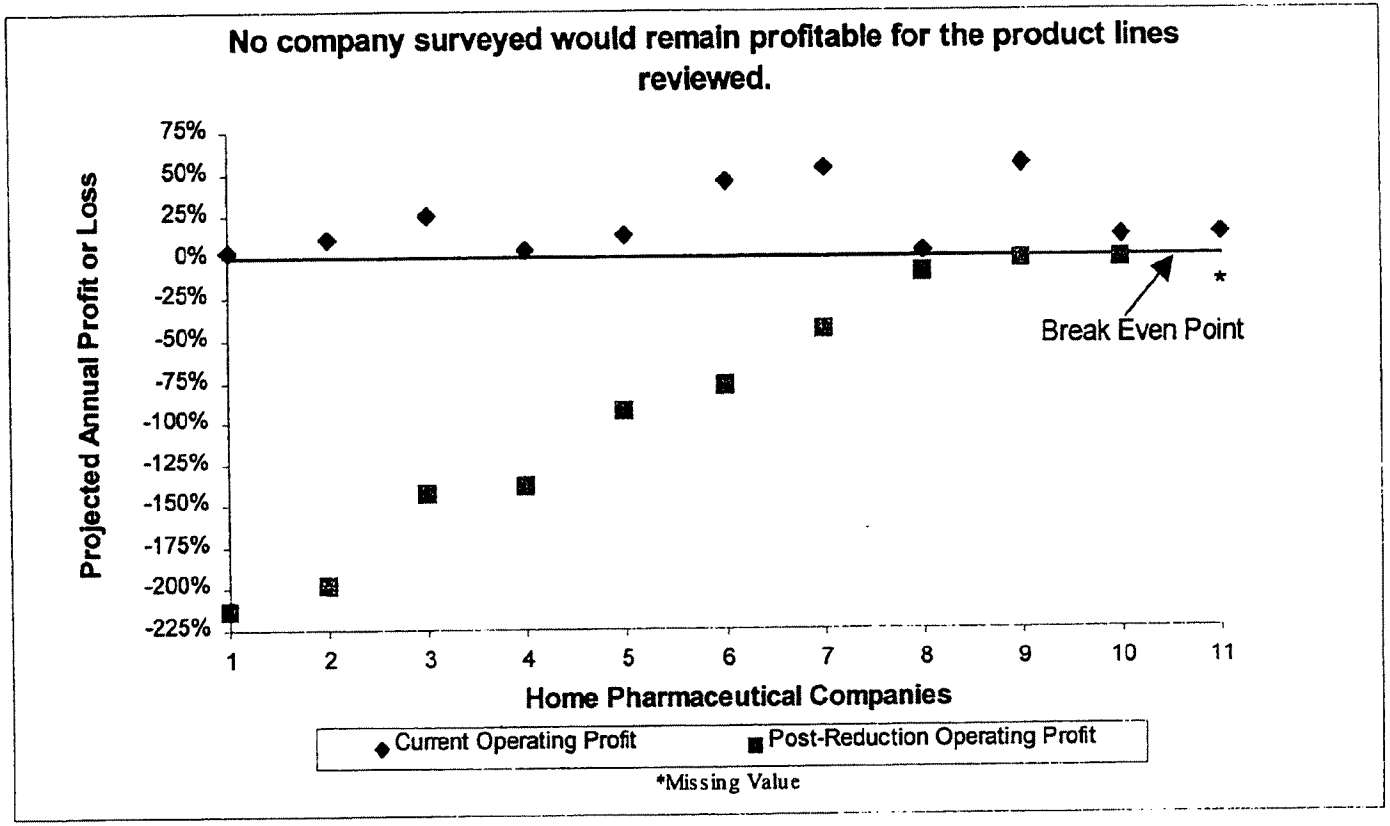

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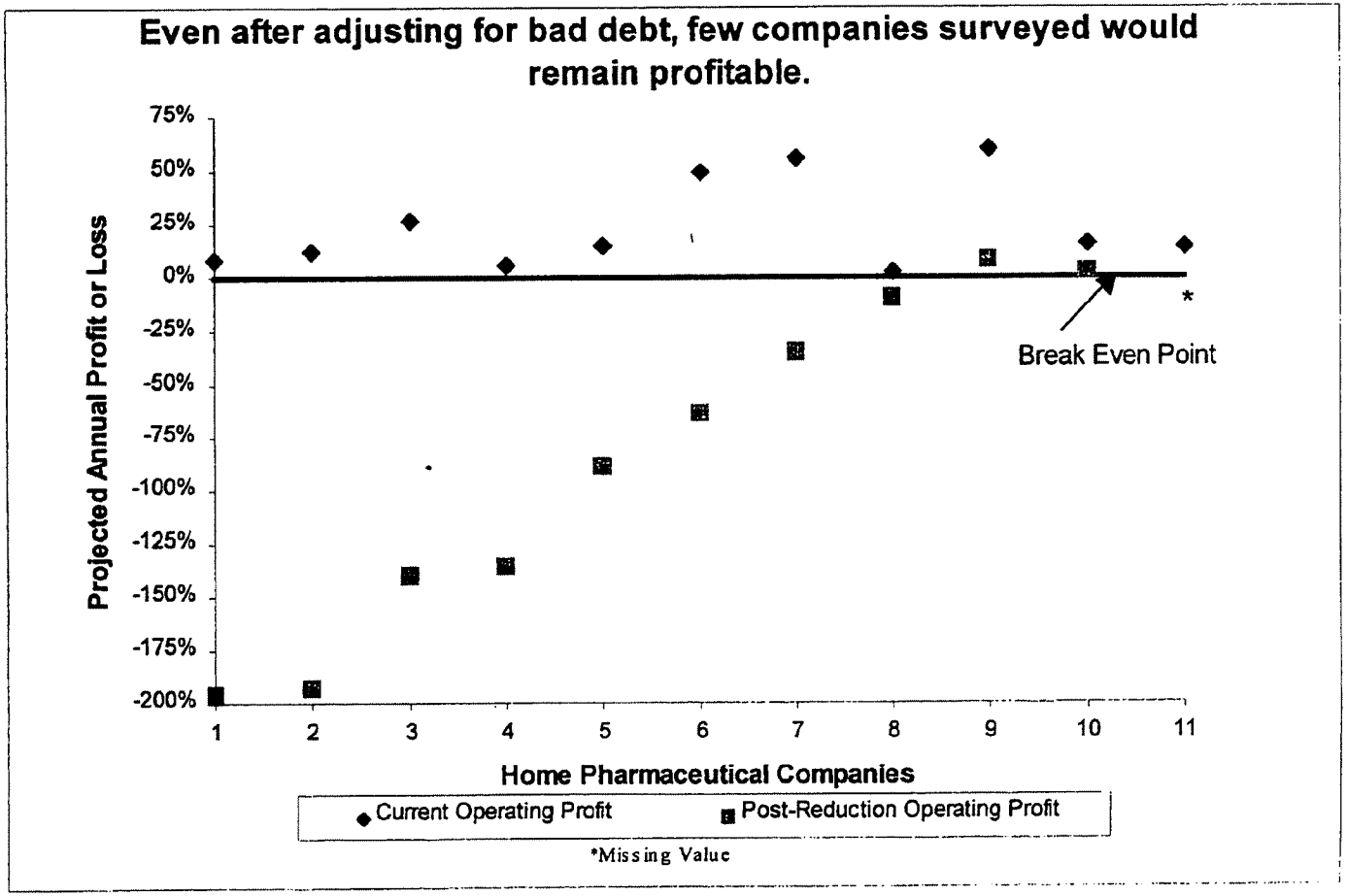
Figure 4: Estimated Initial Financial Impact of AWP Reductions for Respiratory and Infusion Drug Therapies to Medicare and Medicaid Patients at Home (excluding bad debt)

The LEWIN GROUP



Sample Size = 11

AWP039-2761

EDOLPHUS "ED" TOWNS
MEMBER OF CONGRESS
10TH DISTRICT, NEW YORK

COMMERCE
HEALTH AND THE ENVIRONMENT
RANKING MEMBER
FINANCE AND HAZARDOUS MATERIALS

GOVERNMENT REFORM
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September 27, 2000

The Honorable Donna E. Shalala
Secretary
The U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Shalala:

We are writing to express our concern about the Administration's planned cuts of Medicare drug payments, which will create hardship for the African-American Medicare beneficiaries suffering from respiratory diseases including asthma, emphysema, bronchitis and chronic obstructive pulmonary disease (COPD).

The September 8, 2000 letter from Nancy-Ann Min DeParle, HCFA Administrator, to Members of Congress detailed HCFA's instructions to its DME regional carriers to radically reduce the average wholesale price (AWP) of certain Medicare reimbursed drugs including albuterol. HCFA excluded cancer and hemophilia drugs to gather more information about appropriate pricing. The reductions made on the remaining drugs were based on Department of Justice (DOJ) Medicaid fraud control unit data. This pricing change directed by HCFA will result in a 66% reduction to the respiratory medication, albuterol. This reduction will effectively force the current Medicare providers of home respiratory medications out of business and eliminate this benefit for the African-American community.

This policy will have a disproportionate and adverse effect on African-Americans with serious respiratory diseases. Please consider the following:

African-Americans have a higher smoking rate than the majority population. Nearly seven million African-Americans smoke in the United States, representing 27% of the adult African-American population. More than 80% of chronic obstructive pulmonary disease is caused by smoking. COPD is the 4th leading cause of death in the United States and occurs predominately in the 65 and over population.

African-American mortality rates from respiratory diseases, particularly for females, are on the rise, according to the National Center for Health Statistics.

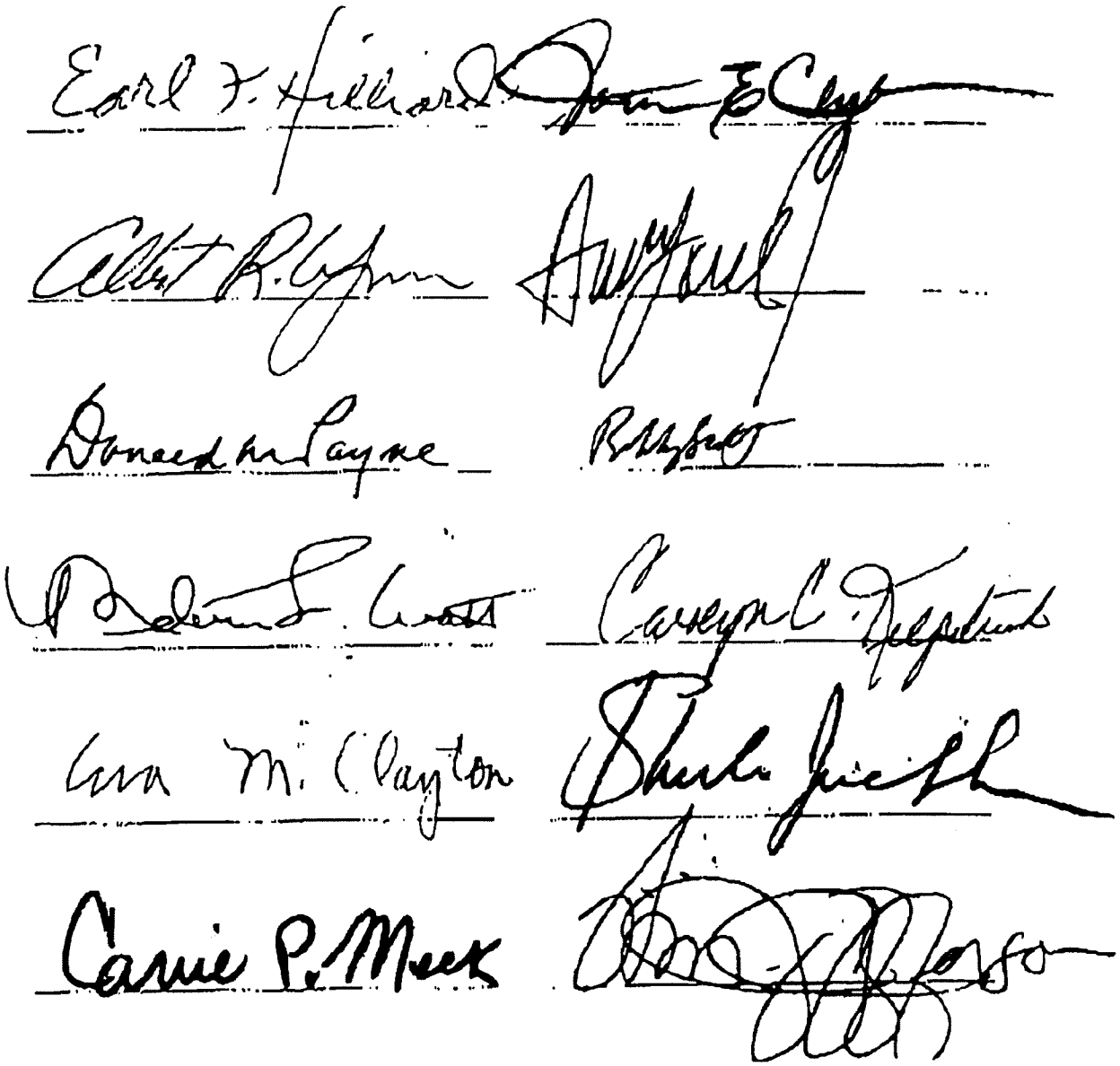
African-American Medicare-eligible beneficiaries generally are not able to pay for their medications, and this benefit is essential to their continued health.

African-Americans suffering from respiratory diseases will be forced to access healthcare in the most acute and expensive settings the emergency room and hospitalization. Additionally, this unnecessary disruption to the family will create great hardship.

The real-world impact of HCFA's instruction to its DMERCs is the creation of two distinct classes of Medicare patients receiving medications -- 1) beneficiaries receiving medications excluded by the instructions, and 2) beneficiaries receiving medications affected by these instructions. The latter group will no longer have access to these medications through Medicare, since no provider will be able to supply these products at the new reimbursement levels dictated by this instruction.

HCFA's instruction clearly harms African-American Medicare beneficiaries who need respiratory medications. This will force these beneficiaries to make life choices between food and medication. They cannot afford to pay for these medications at their pharmacy. Therefore, we strongly urge you to rescind this decision immediately and order a careful study into the impact of cuts on patient access and quality of care.

Sincerely,



Congress of the United States

Washington, DC 20515

July 20, 2000

The Honorable Donna Shalala
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Madam Secretary:

We strongly support efforts to combat waste, fraud, and abuse in the Medicare program – our seniors deserve nothing less than the best Medicare program possible. However, we also have serious concerns about changes which, though intended to improve efficiency and good management, threaten to jeopardize patient access to quality care.

The Administration has recently announced its plans to reduce Medicare reimbursement for cancer and other therapies by substantially reducing the calculation of their average wholesale price. The Health Care Financing Administration's decision to undertake this change with no corresponding correction of the Medicare program's severe underpayment of the expenses associated with administering those therapies is both unwarranted and unsound.

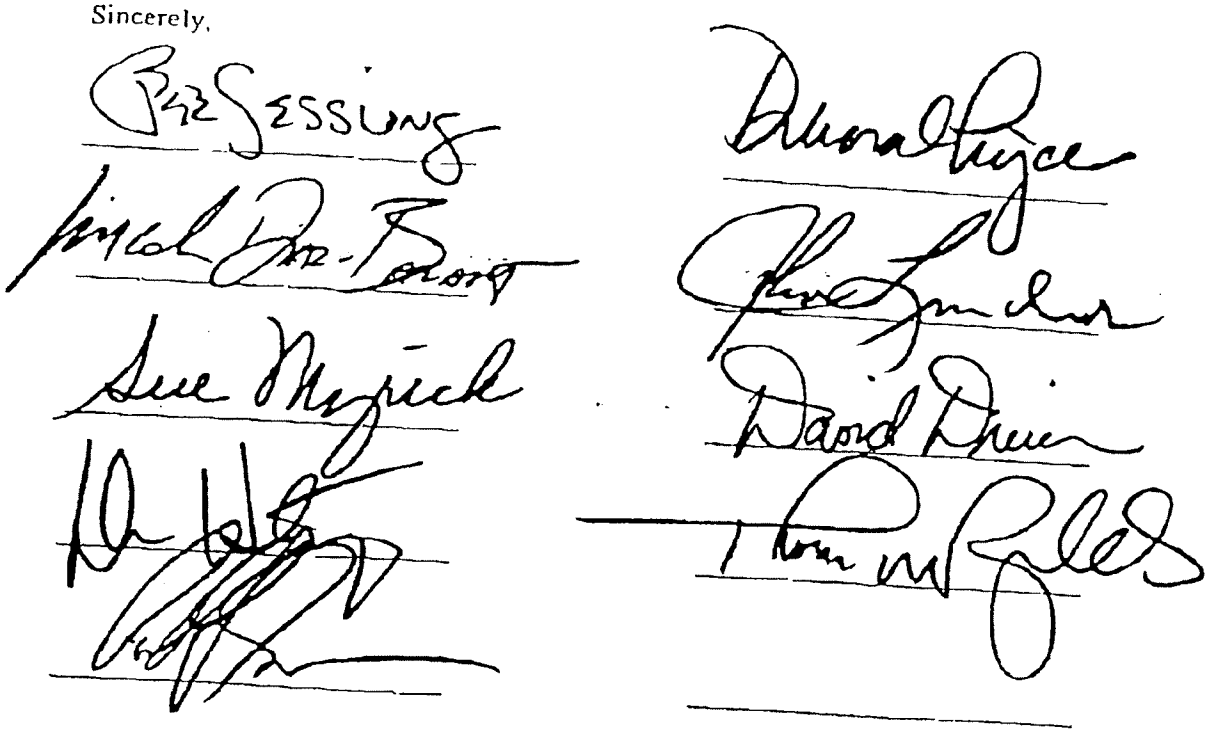
As you know, considerable attention has been paid by Congress, the General Accounting Office, the cancer community, and HCFA itself to the flaws that plague Medicare's reimbursement of non-drug cancer care services. In many cases, reimbursement for the essential services provided by such office staff as oncology nurses is either nonexistent or far from adequate. As a result, the program greatly underpays oncology practices for the care they provide to Medicare beneficiaries with cancer. This inequity has been identified for over a decade, but no sufficient correction has been made.

That is why we are concerned about HCFA's plans to reduce Medicare reimbursement for cancer and other therapies starting October 1st. This source of funding has been a crucial safeguard enabling providers to serve patients despite the Medicare program's underpayment of drug administration and other essential services. Since the Agency's plans do not include a long-overdue correction of this underpayment, the reduction in reimbursement for drugs would result in a devastating loss to providers and pose an unprecedented risk to patients.

Such a loss would be unsustainable for anyone – and particularly for the small medical groups and community clinics that today provide the vast majority of cancer care in America. As a result, community-based providers would no longer be able to serve their patients in either private practice or hospital outpatient settings. Instead, seniors with cancer would have to seek care in more-expensive inpatient hospital settings, although even this option may be unavailable due to existing coverage restrictions. The result would be less accessible care for seniors and even higher costs for the Medicare program.

We cannot afford to take this risk. As a result, we are urging you to rescind the Health Care Financing Administration's plan to alter the Medicare program's reimbursement of cancer and other therapies until such time as the Agency, together with patients, providers, and Congress, fully examines the impact of this plan and the best manner to ensure adequate reimbursement and patient access to care.

Sincerely,



United States Senate

WASHINGTON, DC 20510

August 1, 2000

Honorable Donna E. Shalala
Secretary
The U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Shalala:

We are writing to request clarification of the Administration's recent policy statements concerning Medicare reimbursement for certain covered pharmaceuticals and other related products.

We are concerned about this change and believe this policy could limit beneficiaries' access to care at their doctor's office or in their homes, thus resulting in patients receiving treatment through more expensive hospital stays.

It is unclear to us what methodology was used by the Department in recalculating reimbursement levels and how these prices will be integrated into the current statutory mechanism for reimbursing prescription drug providers. Therefore, we would appreciate your providing us with information concerning the methodology used to revise the Average Wholesale Price (AWP), its impact on First Data Bank's current contracts with subscribers, its effect on private insurance contracts, and the impact of reloading data onto computer systems for HCFA, state Medicaid programs, and private insurance companies.

We share your objective to ensure that Medicare should pay a fair price for prescription drugs. Therefore, before implementing new payment levels, we encourage you to initiate a dialogue with the Congress, provider groups and beneficiaries to better assess their potential impact on Medicare spending and beneficiary health care.

We look forward to hearing from you as soon as possible.

Sincerely,

JOHN BREAUX

BILL FRIST

ORRIN HATCH

MARY LANDRIEU

MAX BAUCUS

AMERICAN ASSOCIATION FOR HOMECARE

Formerly the Organizations of HIDA Home Care, HHSSA and NAMES

Supporting Quality Health Care Services at Home

Via Hand Delivery

June 23, 2000

The Honorable Donna E. Shalala
Secretary of Health and Human Services
200 Independence Avenue
Washington, D.C. 20201

Re: **Proposed Revision of Calculation of Average Wholesale Price**

Dear Madam Secretary:

The American Association for Homecare (AAH) is concerned by your recent proposal to revise the methods used by the Department of Health and Human Services (HHS) to calculate the average wholesale price (AWP) of drugs, which is used as the basis for payment of claims under Medicare Part B. This proposal would implement a fundamental change to the system in a very short time. It fails to take into account the unique characteristics and sales patterns of a number of drug products, especially infusion and respiratory products used in a home setting, and would result in substantial underpayment and financial harm to many suppliers.

AAH was created by the merger earlier this year of the home care section of the Health Industry Distributors Association (HIDA), the Home Health Services and Staffing Association (HHSSA), and the National Association for Medical Equipment Services (NAMES). AAH represents all segments of the home care industry, including suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), and home health agencies. Our members provide a wide a range of services to Medicare beneficiaries in their homes, including respiratory and infusion therapies. The majority of Medicare beneficiaries served by AAH members are elderly, frail and sick.

The HHS proposal to revise its calculation of AWP for the Medicare Part B program was set forth in a letter to Congressman Bliley, Chairman of the House Commerce Committee, dated May 31, 2000. According to the letter, HHS will ask carriers to use "more accurate data on average wholesale prices." While the letter remains vague about

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the precise methodology that HHS will use to implement these pricing changes, it appears that this new "AWP" was derived by the Department of Justice from catalogs of drug wholesalers for approximately 400 national drug codes. The Department of Justice reportedly obtained this information during investigations and provided it to First Data Bank, a company that specializes in compilation of drug pricing data.

HHS plans to forward the "average" of the wholesale catalog prices to its Medicare carriers for use in determining AWP for their next quarterly update of Medicare drug allowances, which will become effective on October 1, 2000. This substantial shift in policy will be accomplished in a matter of a few months, without notice and comment rulemaking or other formal public input.

This proposal applies a kind of "one size fits all" remedy to an industry that provides a diverse range of items and services. We are particularly troubled by the haste with which the change would be made. The existence of the disparity between AWP pricing and physician acquisition cost has been known for quite some time. As long ago as 1968, a report by the then Department of Health Education and Welfare stated that wholesalers, retailers, hospitals and government agencies often pay markedly different prices for the same drug and dosage form. It expressly acknowledged that the Red Book and Blue Book do not reflect actual manufacturers' prices to wholesalers and retailers.[1] Over the ensuing three decades, government reports repeatedly commented on the gap between AWP and prices charged in actual industry transactions.[2] Throughout this time, potential remedies have been proposed, reconsidered, abandoned and reproposed. No one proposal, however, has been examined in depth.

In light of this history, it is difficult to understand why HHS's most recent proposal needs to be put into effect so rapidly. While HHS has for years stated its belief that the AWP-based system should change, it never has fully considered the costs associated with providing different drug products under varying scenarios. The rush to implement the proposed change leaves HHS little time to assess the different settings in which drug delivery takes place, or to consider the potential impact on suppliers of the drastic changes. For a number of products, pricing and contracts reflect more than the simple provision of the drug product itself. For drug therapies administered in the home, regular and ongoing intervention by homecare providers is critical to ensuring that patients achieve the maximum benefit from the prescribed therapy. The acquisition costs of the drugs alone do not accurately reflect these essential features of the therapeutic regimen.

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1 Department of Health Education and Welfare, Task Force on Prescription Drugs, "The Drug Makers and the Drug Distributors," (Dec. 1968).

2 See, e.g., 39 Fed. Reg. 41480 (Nov. 27, 1974) ("Red Book data, Blue Book data (i.e., AWP) and other standard prices . . . were frequently in excess of actual acquisition cost."); Office of Inspector General, HHS, "Changes to Medicaid Prescription Drug Program Could Save Millions," (Sept. 1984) (stating that pharmacies purchased most drugs at an average of 15.9% below AWP); Office of Inspector General, HHS, "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Maryland Department of Health and Mental Hygiene," (Mar. 1996) (finding that Maryland pharmacies were paying 41.9% below AWP for generic drugs).

Moreover, prior to 1997, the Health Care Financing Administration (HCFA) had the authority to pay for drugs based on the estimated acquisition cost of the drug. As your letter to Chairman Bliley acknowledges, determining a statistically valid estimate of acquisition costs was so administratively complex that HCFA reverted to using the AWP as a basis for Medicare prescription drug reimbursement. Consequently, in 1997, the Administration proposed to Congress that Medicare change reimbursement for drugs to the acquisition cost of the drug. Congress considered this proposal and specifically rejected it in favor of the AWP in the Balanced Budget Act (BBA) of 1997. Section 4556 of the BBA established that Medicare would reimburse prescriptions drugs at ninety-five percent (95 %) of the AWP for the drug[3]. Although the Administration tried again in 1998 to change the Medicare payment system for drugs from AWP to acquisition costs, your letter correctly notes that Congress did not act on this proposal.

As we noted above, your letter to Chairman Bliley is vague about the precise methodology that was used to develop this new, "more accurate pricing" for prescription drugs. We remain concerned that the new pricing information is an attempt to recast acquisition costs as the AWP. A proposal to shift immediately and across-the-board to an acquisition cost basis for Medicare Part B drug reimbursement would cause substantial harm to Medicare suppliers and the beneficiaries they serve. In many instances, they would be forced to provide these products and services at a loss. Ultimately, they could have to abandon providing these services. Beneficiaries would be forced to receive these services in a more expensive (and inconvenient) institutional setting, increasing the overall Medicare program costs.

Any attempt to use the acquisition cost as a basis for calculating AWP would constitute a significant departure from established policy and would be contrary to the statutory mandate established by the BBA. We acknowledge that there is no definitive regulatory or statutory definition for AWP, and that, over the years, it has been open to interpretation. We note, however, that AWP has never been understood to represent the acquisition cost of a drug. Indeed, when Congress adopted section 4556, it expressly understood that the AWP of drug was not its acquisition cost, especially in light of its rejection of the Administration's proposal. The leap from the current calculation and understanding of AWP to an acquisition costs-based system would be a broad one. AAH is concerned that HHS has not fully considered and understood the real world effects of making such a jump.

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3 HCFA published a notice of proposed rulemaking in the Federal Register to implement this statutory mandate. 63 Fed. Reg. 58813, 58849. HCFA instructed the carriers on the procedure for determining AWP in a Program Memorandum dated January 1998, PM AB 97-25.

We would be happy to meet with you to discuss the impact that this proposed policy would have on the industry, and to suggest potential modifications that could address unintended consequences. Thank you for your attention to this issue. We look forward to hearing from you.

Sincerely,

Asela M. Cuervo
Vice President Government Affairs